

Rule Summary and Fiscal Analysis (Part A)**State Medical Board**

Agency Name

Division

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4731-11-04

Rule Number

NEW

TYPE of rule filing

Rule Title/Tag Line

**Controlled substances: Utilization of short term anorexiant
for weight reduction.****RULE SUMMARY**

1. Is the rule being filed for five year review (FYR)? **No**
2. Are you proposing this rule as a result of recent legislation? **No**
3. Statute prescribing the procedure in accordance with the agency is required to adopt the rule: **119.03**
4. Statute(s) authorizing agency to adopt the rule: **4731.05**
5. Statute(s) the rule, as filed, amplifies or implements: **4731.22**
6. State the reason(s) for proposing (i.e., why are you filing,) this rule:

New rule 4731-11-04 regulates the utilization of schedule III and IV controlled substance stimulants for short term weight loss (short term anorexiant) in the treatment of obesity. Ohio has seen exploding numbers of prescriptions for controlled substances that can feed illegal diversion and abuse of those medications. The Medical Board's goal in proposing the new rule is to balance the needs of those Ohioans who need controlled substances for legitimate medical purposes against the need to limit controlled substance access in order to reduce

diversion and addiction. The proposed rule is intended to strike the proper balance in that approach.

7. If the rule is an AMENDMENT, then summarize the changes and the content of the proposed rule; If the rule type is RESCISSION, NEW or NO CHANGE, then summarize the content of the rule:

New rule 4731-11-04 regulates the utilization of controlled substance stimulants by physicians for the treatment of obesity using drugs for which the FDA approved labeling indicates the usage is for "a few weeks." The rule continues to define "a few weeks" as twelve weeks and requires that a physician utilizing short term anorexiant follow the FDA approved labeling instructions. The rule also requires that the patient have made a good faith effort to lose weight through caloric reduction, nutritional counseling, behavior modification, and exercise prior to being prescribed controlled substances, requires periodic evaluations of the patient, sets out reasons for discontinuation of the short term anorexiants, and requires that a physician check OARRS prior to utilizing short term anorexiants.

8. If the rule incorporates a text or other material by reference and the agency claims the incorporation by reference is exempt from compliance with sections 121.71 to 121.74 of the Revised Code because the text or other material is **generally available** to persons who reasonably can be expected to be affected by the rule, provide an explanation of how the text or other material is generally available to those persons:

The references Section 4731.22 of the Revised Code, which is readily available via an internet search and from the Medical Board's website.

9. If the rule incorporates a text or other material by reference, and it was **infeasible** for the agency to file the text or other material electronically, provide an explanation of why filing the text or other material electronically was infeasible:

Not applicable.

10. If the rule is being **rescinded** and incorporates a text or other material by reference, and it was **infeasible** for the agency to file the text or other material, provide an explanation of why filing the text or other material was infeasible:

Not Applicable.

11. If **revising** or **refiling** this rule, identify changes made from the previously

filed version of this rule; if none, please state so. If applicable, indicate each specific paragraph of the rule that has been modified:

Not Applicable.

12. Five Year Review (FYR) Date:

(If the rule is not exempt and you answered NO to question No. 1, provide the scheduled review date. If you answered YES to No. 1, the review date for this rule is the filing date.)

NOTE: If the rule is not exempt at the time of final filing, two dates are required: the current review date plus a date not to exceed 5 years from the effective date for Amended rules or a date not to exceed 5 years from the review date for No Change rules.

FISCAL ANALYSIS

13. Estimate the total amount by which *this proposed rule* would **increase / decrease** either **revenues / expenditures** for the agency during the current biennium (in dollars): Explain the net impact of the proposed changes to the budget of your agency/department.

This will have no impact on revenues or expenditures.

0.00

Not applicable.

14. Identify the appropriation (by line item etc.) that authorizes each expenditure necessitated by the proposed rule:

Not applicable.

15. Provide a summary of the estimated cost of compliance with the rule to all directly affected persons. When appropriate, please include the source for your information/estimated costs, e.g. industry, CFR, internal/agency:

There is no cost for the physician who appropriately monitors patients who are on controlled substances.

16. Does this rule have a fiscal effect on school districts, counties, townships, or municipal corporations? **No**

17. Does this rule deal with environmental protection or contain a component dealing with environmental protection as defined in R. C. 121.39? **No**

S.B. 2 (129th General Assembly) Questions

18. Has this rule been filed with the Common Sense Initiative Office pursuant to R.C. 121.82? **Yes**

19. Specific to this rule, answer the following:

A.) Does this rule require a license, permit, or any other prior authorization to engage in or operate a line of business? **No**

B.) Does this rule impose a criminal penalty, a civil penalty, or another sanction, or create a cause of action, for failure to comply with its terms? **Yes**

Violation of the rule may result in administrative licensure discipline for the physician. Discipline might include reprimand, suspension of the license, required course work, and/or revocation of the license. The cost of course work is borne by the licensee.

C.) Does this rule require specific expenditures or the report of information as a condition of compliance? **No**